STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR MEDICAL SERVICES

Office of Pharmacy Services Prior Authorization Criteria

VIEKIRA PAK™ (ombitasvir/paritaprevir/ritonavir + dasabuvir)

Effective 1/28/2016

Prior Authorization Request Form
Prior Authorization Continuation Request Form
Patient Consent Form
Preferred HepC Regimens (Attachment A)

Viekira Pak™ with or without ribavirin is indicated for the treatment of patients with genotype 1 chronic hepatitis C virus (HCV) infection including those with compensated cirrhosis. The product includes ombitasvir, a hepatitis C virus NS5A inhibitor, paritaprevir, a hepatitis C virus NS3/4A protease inhibitor, ritonavir, a CYP3A inhibitor (used as a booster), and dasabuvir, a hepatitis C virus non-nucleoside NS5B palm polymerase inhibitor.

Criteria for Approval

1) All documentation must be fully completed, including the patient consent form. A fibrosis score substantiated by a validated evidence-based method must be reported when requesting prior authorization; **AND**

2) Patient must have a documented **fibrosis level ≥ F3**; **AND**

3) Patient must be eighteen (18) years of age or older; **AND**

4) Viekira Pak™ must be prescribed by, or in conjunction with, a board certified gastroenterologist, hepatologist or infectious disease physician; **AND**

5) Patient must be diagnosed with chronic Hepatitis C Genotype 1; **AND**

6) Patient has abstained from the use of illicit drugs and alcohol for a minimum of three (3) months, as indicated by their signature on the Patient Consent form; **AND**

7) Patient must agree to complete the full regimen and the patient and the provider must agree that an SVR12 and SVR24 will be collected and submitted to WV Medicaid to verify therapy success;

Duration of Approval

- A list of accepted regimens and treatment duration for chronic Hepatitis C therapy may be found in Attachment A.

- Initial approval is for 6 weeks and requires submission of the starting HCV RNA level

- Continued coverage after week 6 depends upon receipt of an HCV RNA level at treatment week 4 (TW4), documentation of patient compliance, continued abstinence and an HCV RNA < 25 IU/ml. **Failure to obtain and report a treatment week 4 HCV RNA load will result in denial of further coverage.**

Diagnostic/Disease Severity Evidence (must be attached to request)

1) Cirrhosis may be substantiated either through biopsy or the presence of **at least two** of the following clinical features:
    a. Cirrhotic features on imaging (MRI, ultrasound, or CT)
    b. Ascites
    c. Esophageal varices
    d. Reversed AST:ALT ratio (> 1), thrombocytopenia (< 130,000 platelets/μL), and coagulopathy (INR > 2)

Criteria for Denial

1) Prior authorization requests submitted with incomplete documentation will be denied.

2) Failure to report a fibrosis score.

3) Patient has Child-Pugh score of B or C.

4) Evidence exists that the patient has abused any illicit substance or alcohol in the past three (3) months.

5) Patient has been previously treated with **ombitasvir/paritaprevir/ritonavir + dasabuvir.**

6) Patient is taking a concomitant medication that has a significant clinical interaction with Viekira Pak™ (refer to package insert for a listing of interacting medications).

7) **Requests for continuation of coverage will be denied if the patient has an HCV RNA level >25 IU/ml OR if the prescriber has not submitted or has not obtained a viral load at treatment week 4.**

Additional Considerations

1) Coverage shall be for one successful course of therapy in a lifetime. Success of therapy shall be judged by undetectable SVR12 and SVR24 HCV RNA levels. If RNA levels have not been submitted, then it will be assumed that therapy was successful. Re-infection will not be covered. Exceptions may be allowed on a case-by-case basis.

2) It is highly recommended that the patient vaccinated against Hepatitis A and Hepatitis B.

3) Lost or stolen medication replacement request will not be authorized.

References

1) Viekira Pak™ [package insert]. Abbvie, Revised 4/2016
2) AASLD 2015 Recommendations for Testing, Managing and Treating Hepatitis C (http://www.hcvguidelines.org)
3) Heidelbaugh JJ and Bruderly M. Cirrhosis and Chronic Liver Failure: Part I. Diagnosis and Evaluation. *Am Fam Physician.* 2006 Sep 1;74(5):756-762.